

WHAT IS CLAIMED IS:

1           1. A device for intracorporeal use within a patient's body, comprising:  
2           an implantable scaffold;

3           at least one source of at least one therapeutic capable agent associated with the  
4           scaffold and configured to release the therapeutic capable agent within the patient's body at a  
5           controlled rate; and

6           a rate-controlling element layer covering at least a portion of the source and  
7           including at least one therapeutic capable agent and providing for an initial relatively more  
8           rapid release of the at least one therapeutic capable agent therapeutic from the rate-controlling  
9           element layer as well as a sustained, controlled release of the at least one therapeutic capable  
10          agent from the source.

1           2. A device for intracorporeal use within a patient's body, comprising:  
2           an implantable scaffold;  
3           at least one source of at least one therapeutic capable agent associated with the  
4           scaffold ; and

5           a rate-controlling element disposed adjacent at least a portion of the source  
6           and being configured to control the release of the therapeutic capable agent in the patient's  
7           body at an initial rate and at a subsequent rate relatively slower than the initial rate.

1           3. A device as in Claim 1 or 2 wherein the rate-controlling element  
2          covers the source.

1           4. A device as in Claim 1 or 2 wherein the rate-controlling element  
2          covers only a portion of the source.

1           5. A device as in Claim 1 or 2 wherein the source comprises a reservoir.

1           6. A device as in Claim 5 wherein the reservoir is at least partially  
2          disposed over the expandable structure.

1           7. A device as in Claim 1 or 2 wherein the scaffold comprises a tissue  
2          facing and a luminal facing surface.

1           8. A device as in Claim 7 wherein the reservoir is disposed adjacent the  
2          luminal facing surface.

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1           9.       A device as in Claim 7 wherein the reservoir is disposed adjacent the

2 tissue facing surface.

1           10.      A device for intracorporeal use within a patient's body, comprising:

2           a radially expandable implantable scaffold having a plurality of regions

3           exhibiting different mechanical profiles during the expansion of the scaffold and including  
4           relatively lower and relatively higher mechanical profiles; and

5           a source of at least one therapeutic capable agent comprising a plurality of

6           segments and disposed adjacent at least a portion of the scaffold.

1           11.      A device as in Claim 10 wherein the segments are disposed adjacent

2 the relatively lower mechanical profile regions.

1           12.      A device as in Claim 10 wherein the segments are disposed adjacent

2 the relatively higher mechanical profile regions.

1           13.      A device as in Claim 10 wherein the segments are disposed adjacent

2 only the regions that do not undergo substantial bending, flexing, stretching, or compressing  
3 upon the expansion of the scaffold.

1           14.      A device as in Claim 10 wherein the segments are disposed adjacent

2 only the regions that do not undergo more than about 5% of bending, flexing, stretching, or

3 compressing upon the expansion of the scaffold.

1           15.      A device as in Claim 10 wherein the segments are disposed adjacent

2 only the regions that undergo substantial bending, flexing, stretching, compressing upon the

3 expansion of the scaffold.

1           16.      A device as in Claim 10 wherein the areas exhibiting relatively higher

2 mechanical profile are configured to be in a direct flow of body fluids flowing through the

3 intracorporeal body.

1           17.      A device as in Claim 10, 13, or 16 further comprising a rate-controlling

2 element disposed adjacent the scaffold.

1           18.      A device as in Claim 17 wherein the rate-controlling element is

2 disposed adjacent at least a portion of the source.

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1               19. A device as in Claim 17 wherein the rate-controlling element is formed  
2 from a nonporous material.

1               20. A device as in Claim 18 wherein the rate-controlling element has a  
2 variable thickness.

1               21. A device as in Claim 20 wherein the rate-controlling element has a  
2 greater thickness adjacent scaffold regions having relatively higher mechanical profile.

1               22. A device for intracorporeal use within a patient's body, comprising:  
2                   an implantable scaffold;  
3                   at least one source of at least one therapeutic capable agent associated with at  
4                   least a portion of the scaffold and configured to release the therapeutic capable agent within  
5                   the patient's body; and  
6                   a rate-controlling element disposed adjacent at least a portion of the source  
7                   and including at least one disruption sufficiently large to permit material transport to or from  
8                   the source.

1               23. A device as in Claim 22 wherein the at least one disruption is an  
2 aperture.

1               24. A device as in Claim 22 or 23 wherein the at least one disruption is  
2 preformed.

1               25. A device as in Claim 22 or 23 wherein the at least one disruption is  
2 formed in the patient's body.

1               26. A device as in Claim 22 or 23 wherein the transport comprises at least  
2 one of transport of native fluids to the source or of the therapeutic capable agent from the  
3 source.

1               27. A device for intracorporeal use within a patient's body, comprising:  
2                   an implantable scaffold;  
3                   at least one source of at least one therapeutic capable agent associated with at  
4                   least a portion of the scaffold and configured to release the therapeutic capable agent within  
5                   the patient's body; and

6                   a rate-controlling element disposed adjacent at least a portion of the source  
7 and being configured to mechanically change upon application of mechanical stress or strain.

1                   28.       A device for intracorporeal use within a patient's body, comprising:  
2                   an implantable scaffold;  
3                   at least one source of at least one therapeutic capable agent associated with at  
4                   least a portion of the scaffold and configured to release the therapeutic capable agent within  
5                   the patient's body; and

6                   a rate-controlling element disposed adjacent at least a portion of the source  
7 and which undergoes a mechanical change upon being implanted in the patient's body.

1                   29.       A device as in Claim 27 or 28 wherein the mechanical change is one of  
2                   mechanical fracture.

1                   30.       A device as in Claim 27 or 28 wherein the mechanical change is one of  
2                   change in surface characteristic.

1                   31.       A device as in Claim 27 or 28 wherein the mechanical change is one of  
2                   change in porosity.

1                   32.       A device as in Claim 27 wherein the mechanical stress or strain is  
2                   applied upon the bending of the scaffold.

1                   33.       A device as in Claim 27 wherein the mechanical stress or strain is  
2                   applied upon the expansion of the scaffold.

1                   34.       A device for intracorporeal use within a patient's body, comprising:  
2                   an implantable scaffold;  
3                   at least one source of at least one therapeutic capable agent associated with at  
4                   least a portion of the scaffold and configured to release the therapeutic capable agent within  
5                   the patient's body; and

6                   a swellable rate-controlling element disposed adjacent at least a portion of the  
7                   source.

1                   35.       A device as in Claim 34 wherein the rate-controlling element swells  
2                   upon exposure to the intracorporeal environment.

- 1                   36. A device as in Claim 35 wherein the rate-controlling element is  
2 configured to release the therapeutic capable agent from the source.
- 1                   37. A device as in any one of Claims 1, 10, 22, or 27 wherein the device  
2 comprises a stent.
- 1                   38. A device as in Claim 37 wherein the stent comprises metallic material.
- 1                   39. A device as in Claim 37 wherein the stent comprises polymeric  
2 material.
- 1                   40. A device as in Claim 39 wherein the stent comprises a degradable  
2 material.
- 1                   41. A device as in Claim 39 wherein the stent comprises a non-degradable  
2 material.
- 1                   42. A device as in Claim 37 wherein the device is balloon-expandable.
- 1                   43. A device as in Claim 37 wherein the device is self-expandable.
- 1                   44. A device as in Claim 37 wherein the source comprises a matrix.
- 1                   45. A device as in Claim 44 wherein the matrix includes a matrix material.
- 1                   46. A device as in any one of Claims 1, 10, 22, 27, or 37 wherein the rate-  
2 controlling element is formed from a nonporous material.
- 1                   47. A device as in Claim 46 wherein the porosity of the rate-controlling  
2 element changes upon implanting in the patient's body.
- 1                   48. A device as in Claim 1, 10, 22, 27, or 37 wherein the rate-controlling  
2 element is formed from a porous material.
- 1                   49. A device as in Claim 46 or 47 wherein the rate-controlling element  
2 comprises a parylene polymer or copolymer.
- 1                   50. A device as in Claim 48 wherein the parylene comprises parylene C.

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1               51. A device as in Claim 46 wherein the rate-controlling element becomes  
2 at least partially porous upon expansion of the scaffold.

1               52. A device as in Claim 46 or 48 wherein a rate of release of the  
2 therapeutic capable agent from the device in an unexpanded state in the patient's body is  
3 different than that in an expanded state.

1               53. A luminal prosthesis comprising:  
2                 a scaffold which is implantable within a body lumen;  
3                 a substance-containing reservoir positioned over at least a portion of a surface  
4 of the scaffold; and  
5                 a rate-controlling element layer covering at least a portion of the substance-  
6 containing reservoir, the rate-controlling element layer having the substance dispersed therein  
7 and providing for an initial rapid release of the substance from the rate-controlling element  
8 layer as well as a sustained, controlled release of the substance from the reservoir.

1               54. A luminal prosthesis comprising:  
2                 a scaffold which is implantable in a body lumen, said scaffold being radially  
3 expandible and having regions which undergo greater and lesser mechanical stress or strain  
4 during radial expansion; and  
5                 a substance-containing reservoir or layer comprising individual portions which  
6 are preferentially positioned over the regions which undergo lesser stress or strain.

1               55. A luminal prosthesis as in Claim 54, wherein the substance-containing  
2 layer is positioned only on those portions of the scaffold that do not substantially bend,  
3 stretch, or compress when the scaffold is expanded.

1               56. A luminal prosthesis as in Claim 54, further comprising a rate-  
2 controlling element layer formed over at least a portion of the scaffold.

1               57. A luminal prosthesis as in Claim 56, wherein the rate-controlling  
2 element layer is thicker over regions of greater mechanical profile.

1               58. A luminal prosthesis comprising:  
2                 a scaffold which is implantable within a body lumen;

3                   a substance-containing reservoir positioned over at least a portion of a surface  
4 of the scaffold; and

5                   a rate-controlling element layer covering at least a portion of the substance-  
6 containing reservoir, the rate-controlling element layer having at least one preformed aperture  
7 which is sufficiently large to permit the transport of body fluids to the substance-containing  
8 reservoir and/or the release of substance from the reservoir.

1                 59.    A luminal prosthesis comprising:  
2                   a scaffold which is implantable within a body lumen;  
3                   a substance-containing reservoir positioned over at least a portion of a surface  
4 of the scaffold, and

5                   a rate-controlling element layer covering at least a portion of the substance  
6 containing reservoir, the rate-controlling element layer being configured to fracture when  
7 stressed by substantially bending, expanding, stretching, or compressing of the scaffold.

1                 60.    A luminal prosthesis comprising:  
2                   a scaffold which is implantable within a body lumen;  
3                   a substance-containing reservoir positioned over at least a portion of a surface  
4 of the scaffold; and  
5                   a rate-controlling element layer covering at least a portion of the substance  
6 containing reservoir, the rate-controlling element layer being configured to swell to permit  
7 release of substance from the reservoir when exposed to a luminal environment.

1                 61.    A luminal prosthesis comprising:  
2                   a scaffold which is implantable within a body lumen;  
3                   a substance-containing reservoir positioned over at least a portion of a surface  
4 of the scaffold; and  
5                   a rate-controlling element positioned over at least a portion of the surface of  
6 the scaffold and covering less than all of the substance containing reservoir.

1                 62.    A luminal prosthesis as in any of Claims 53 through 61, wherein the  
2 luminal prosthesis comprises a metal stent.

1                 63.    A luminal prosthesis as in Claim 62, wherein the metal stent is balloon  
2 expandable.

1                   64.     A luminal prosthesis as in Claim 62, wherein the metal stent is self-expanding.

1                   65.     A luminal prosthesis as in any of Claims 53 through 61 wherein the substance-containing reservoir comprises a matrix layer including the substance dispersed in a matrix material.

1                   66.     A luminal prosthesis as in Claim 65, wherein the substance and the matrix material have been vapor deposited on the scaffold.

1                   67.     A luminal prosthesis as in any of Claim 53 through 61, wherein the substance-containing layer consists essentially of a homogeneous layer of the substance.

1                   68.     A luminal prosthesis as in Claim 67, wherein the substance has been vapor deposited on the scaffold.

1                   69.     A luminal prosthesis as in any of Claims 53 through 61, wherein the scaffold comprises structural elements having rectangular cross-sections defining four orthogonal surfaces, wherein the drug is positioned on fewer than all of the surfaces.

1                   70.     A luminal prosthesis as in any of Claims 53 through 61, wherein the rate-controlling element is porous.

1                   71.     A luminal prosthesis as in any of Claim 53 through 61, wherein the rate-controlling element is nonporous.

1                   72.     A luminal prosthesis as in any of Claims 53 through 61 further comprising a base layer over at least a portion of the scaffold and at least a portion of the substance-containing layer.

1                   73.     A luminal prosthesis as in any of Claims 53 through 61, wherein the rate-controlling element layer comprises a parylene polymer or copolymer.

1                   74.     A luminal prosthesis as in Claim 73, wherein the parylene has been vapor deposited over the scaffold or a portion thereof.

1                   75.     A luminal prosthesis as in Claim 73, wherein the parylene comprises parylene C.

1           76. A luminal prosthesis as in Claim 73, wherein the parylene is  
2 nonporous.

1           77. A device for intracorporeal use within a patient's body, comprising:  
2           an implantable scaffold;  
3           at least one source of at least one therapeutic capable agent having a degree of  
4           crystallinity less than about 90 % and associated with the scaffold and configured to release  
5           the therapeutic capable agent within the patient's body ; and  
6           a rate-controlling element disposed adjacent at least a portion of the source  
7           and being configured to control the release of the therapeutic capable agent to the patient's  
8           body.

1           78. A device as in Claim 77 wherein the therapeutic capable agent has a  
2 degree of crystallinity less than about 50 %.

1           79. A device for intracorporeal use within a patient's body, comprising:  
2           an implantable scaffold;  
3           at least one source of at least one therapeutic capable agent associated with the  
4           scaffold and configured to release the therapeutic capable agent at a targeted tissue site within  
5           the patient's body; and  
6           a rate-controlling element disposed adjacent at least a portion of the source  
7           and being configured to effectuate a therapeutic capable agent flux density of about  $1.71 \times 10^{-14}$  ug/(cm<sup>2</sup>s) to about  $1.71 \times 10^{-8}$  ug/(cm<sup>2</sup>s).

1           80. A device for as in Claim 79 wherein the flux density ranges from about  
2  $1.71 \times 10^{-14}$  ug/(cm<sup>2</sup>s) to about  $3.43 \times 10^{-9}$  ug/(cm<sup>2</sup>s).

1           81. A device for as in Claim 79 wherein the flux density ranges from about  
2  $8.57 \times 10^{-12}$  ug/(cm<sup>2</sup>s) to about  $3.43 \times 10^{-9}$  ug/(cm<sup>2</sup>s).

1           82. A device for as in Claim 79 wherein the flux density ranges from about  
2  $1.71 \times 10^{-11}$  ug/(cm<sup>2</sup>s) to about  $1.03 \times 10^{-9}$  ug/(cm<sup>2</sup>s).

1           83. A device for intracorporeal use within a patient's body, comprising:  
2           an implantable scaffold;

3                   at least one source of at least one therapeutic capable agent associated with the  
4 scaffold and configured to release the therapeutic capable agent at a targeted tissue site within  
5 the patient's body; and

6                   a rate-controlling element disposed adjacent at least a portion of the source  
7 and being configured to control the release of the therapeutic capable agent in the patient's  
8 body, the device having a residual stress in an unexpanded state less than about 10%.

1                 84.    A device for as in Claim 83 wherein the residual stress is less than  
2 about 5 %.

1                 85.    A device for as in Claim 83 wherein the residual stress is less than  
2 about 1%.

1                 86.    A device for as in Claim 83 wherein the residual stress is less than  
2 about 0.5%.

1                 87.    A method for making a device for intracorporeal use, comprising:  
2                   providing an implantable structure having a first residual stress and including  
3                   a scaffold; and

4                   at least one source of at least one therapeutic capable agent associated with the  
5 scaffold and configured to release the therapeutic capable agent at a targeted tissue site within  
6 the patient's body;

7                   changing the structure residual stress to a second residual stress;  
8                   disposing a rate-controlling element adjacent at least a portion of the source  
9 and being configured to control the release of the therapeutic capable agent in the patient's  
10 body.

1                 88.    A method as in Claim 87 wherein the changing step comprises  
2 reducing the residual stress.

1                 89.    A method as in Claim 87 wherein the changing step comprises  
2 exposing the structure to ultrasound energy for a period of time.

1                 90.    A method as in Claim 87 wherein the changing step comprises  
2 exposing the structure to vibrational energy for a period of time.

1               91.     A method as in Claim 87 wherein the changing step comprises heating  
2     the structure to a first temperature for a period of time.

1               92.     A method as in Claim 91 wherein the first temperature is less than the  
2     melting point of the therapeutic capable agent.

1               93.     A method as in Claim 91 wherein the first temperature is about the  
2     same as the melting point of the therapeutic capable agent.

1               94.     A method as in Claim 91 wherein the at least one therapeutic capable  
2     agent comprises a plurality of therapeutic capable agents and the first temperature is about the  
3     same as the melting point of the therapeutic capable agent with the lowest melting point.

1               95.     A method as in Claim 91 wherein the first temperature is more than the  
2     melting point of the therapeutic capable agent.

1               96.     A method as in Claim 91 wherein the at least one therapeutic capable  
2     agent comprises a plurality of therapeutic capable agents and the first temperature is more  
3     than the melting point of the therapeutic capable agent with the lowest melting point.

1               97.     A method as in Claim 87, 88, 89, 90, 91, 92, 93, or 95 wherein the  
2     changing step is performed before the disposing step.

1               98.     A method as in Claim 87, 88, 89, 90, 91, 92, 93, or 95 wherein the  
2     changing step is performed after the disposing.

1               99.     A method as in Claim 87 wherein the chaning step comprises heating  
2     the structure to a second temperature for a period of time and is performed after the disposing  
3     step.

1               100.    A method as in Claim 99 wherein the heating of the structure to a  
2     second temperate is performed under vacuum.

1               101.    A method as in Claim 99 wherein the heating of the structure to a  
2     second temperate is performed in the absence of oxygen.

1               102.    A method as in Claim 98 wherein the second temperature is less than  
2     the glass transition temperature of the rate-controlling element.

1               103. A method as in Claim 98 wherein the first temperature is about the  
2 glass transition temperature of the rate-controlling element.

1               104. A method as in Claim 98 wherein the first temperature is more than the  
2 glass transition temperature of the rate-controlling element.

1               105. A method as in Claim 87 wherein the changing step comprises the step  
2 of both Claims 91 and 99.

1               106. A device for intracorporeal use within a patient's body, comprising:  
2               an implantable scaffold;  
3               at least one source of at least one therapeutic capable agent associated with  
4               the scaffold and configured to release the therapeutic capable agent within the patient's body;  
5               and  
6               a rate-controlling element layer covering at least a portion of the source and  
7               being formed from a non-porous material.

1               107. A device as in Claim 106, wherein the non-porous material comprises  
2 parylene.

1               108. A device as in Claim 106, wherein the nonporous material becomes at  
2 least partially porous when exposed to conditions in the patient's body.

1               109. A device as in claim 106, wherein the rate-controlling element  
2 becomes disrupted when exposed to conditions in the patient's body.

1               110. A device as in Claim 106, wherein the rate-controlling element  
2 includes a therapeutic capable agent.

1               111. A device as in Claim 110, wherein the therapeutic capable agent in the  
2 rate controlling element is the same as the therapeutic capable agent in the source.

1               112. A device as in claim 106, wherein the nonporous material is selected  
2 from the group consisting of plasma deposited polymers, sputtered materials, evaporated  
3 materials, electroplated metals, electroplated alloys, glow discharge coatings, polyethylenes,  
4 polyurethanes, silicone rubber, cellulose, and parylene.